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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,113	10/23/2001	Eric K. Engelhard	A-70970/RMS/DCF	3901

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,113	ENGELHARD ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 10-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 234 (claims 8 and 9, to the extent they read on SEQ ID NO: 54) in the Paper received October 20, 2004 is acknowledged. The traversal is on the ground(s) that Groups 232 and 233 should be rejoined with the claims of Group 234 since SEQ ID NO: 52, 53 and 54 are genomic, mRNA and coding sequence of the same gene (IRF4), respectively and do not present additional search burden. This is found partially persuasive.

While SEQ ID NO: 53 (mRNA) and SEQ ID NO: 54 (coding sequence) are sequence homologous, these sequences do not share sequence homology with SEQ ID NO: 52. SEQ ID NO: 52, the alleged genomic DNA sequence from which SEQ ID NO: 53 and SEQ ID NO: 54 reportedly descend do not share the sequence homology mandated by the assertion they are the same as inferred in the Response submitted October 20, 2004, see attached alignments between the sequences with particularity the highlighted sections.

Clearly different searches and issues are involved in the in the examination of SEQ ID NO: 52. The restriction between Groups 53 and 54 is absolved and Group 52 will not be joined with these two Groups. For the reasons stated above the restriction requirement is deemed to be proper and is adhered to. Applicant is reminded that the policies set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86 will be followed.

However, the policies set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86 will be followed. Method claims limited to the scope of the allowable product claims will be rejoined and examined at the time the product claims are indicated as being allowable.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-19 are pending.

Claims 1-7 and 10-19, drawn to non-elected inventions are withdrawn from examination.

Claims 8 and 9 are examined on the merits to the extent that the CA protein (CAP) is encoded by the nucleic acid identified as SEQ ID NO: 53 and SEQ ID NO: 54.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' claims are directed to methods of screening for a bioactive agent

capable of binding and modulating the activity of a CA protein (CAP). The written description is not commensurate in scope with these method claims including ambiguous molecules broadly termed bioactive agents, which have not been adequately described nor evidenced to be in the possession of Applicants. "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identify characteristics sufficient to show that the applicant was in possession of the claimed invention", see Official Gazette, 1242 OG 172, January 30, 2001.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

The skilled artisan cannot envision the detailed structure of each and every molecule that could possibly be considered a bioactive agent and conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential

method of isolating it. The product itself is required. Applicants have not fully described bioactive agents with sufficient particularity such that one skilled in the art would recognize that the Applicants had possession of the claimed invention. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 8 and 9 are vague and indefinite in the recitation "bioactive agent". It is not clear what renders an agent as bioactive. It is not clear what criteria one of ordinary skill in the art would use in assessing an agent as bioactive. The metes and bounds of the claims cannot be determined.

Furthermore, a "bioactive agent" can be anything, such as a peptide, an organic molecule, an inorganic molecule, a DNA fragment, a carbohydrate, etc. Applicant's attention is directed to Ex Parte Tanksley (26 USPQ2d 1384) wherein the Board noted that under 35 U.S.C. 112, second paragraph, the claims must be so definite as to allow the comparison with the available art and must also make it possible for the public to determine from the claim what it encompasses. Due to the indefiniteness of the claims one would not know if the patented claimed was being infringed. Applicants are requested to clarify the claim language.

b. The recitation "said candidate agent" in claims 8 and 9, section b lacks proper antecedent bases. Moreover, it is not clear if said candidate agent is the same as the bioactive agent listed in line one of the claims or the candidate bioactive agent listed on line 4.

c. Claim 9 is vague and indefinite in the recitation "bioactivity". The claims do not disclose activities deemed as bioactivities. Accordingly, the metes and bounds of the claim cannot be determined.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 6,245,562 (filed May 28, 1996), and further in view of Harlow and Lane (Antibodies: A Laboratory Manual, pages 139, 174-177, 215, 216, 553, 555-559, Cold Spring Harbor Laboratory, New York, 1988). U.S. Patent #6,245,562 teaches a nucleic acid, Sequence number 13 that is 100% sequence identical to Applicants' SEQ ID NO: 54 and SEQ ID NO: 53. It is reasonable to conclude that sequence 13 would encode the same protein as Applicants' nucleic acid sequence, SEQ ID NO: 54. Sequence #13 encodes a protein identified in the patent as sequence #14 (MUM-2 protein), see columns 37-40. The MUM-2 protein is recognized by an antibody, see attached database sheet; columns 31-38 and column 13, line 58-column 14, line 17. The taught antibody is regarded by the Examiner as a candidate bioactive agent. The taught antibody is directed to a purified MUM-2 protein and capable of specifically recognizing the said protein and subsequently binding the protein. The patent does not teach a method of determining the binding of the candidate agent to the CA protein.

However, Harlow and Lane teach methods of screening for antibodies, bioactive agents and their binding to antigen proteins. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine

the teachings of both the patent and antibody text to assay for antigen/antibody specificity, recognition of antigen determinants and implication of the antigen and antibody in diagnostics or other immunological techniques. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the patent and Harlow that screening for antibodies is routine and further precipitated by establishing information regarding an antigen, such as potential marker for cancer which could reveal knowledge in the areas of diagnosis and antigen characterization.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm, with alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
20 December 2004